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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,793	12/26/2000	Ruedi H. Aebersold	P-IS 4534	3321

23601 7590 05/07/2003

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/07/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,793

Applicant(s)

AEBERSOLD ET AL.

Examiner

My-Chau T. Tran

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 24-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 44-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1639

DETAILED ACTION

1. Applicant's amendment filed 2/18/03 in Paper No. 17 is acknowledged and entered. Claims 1 and 13 are amended by the amendment. Claims 44-50 are added by the amendment.
2. Claims 1-50 are pending.
3. This application contains claims 24-43 are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
4. Claims 1-23 and 44-50 are treated on the merit in this Office Action.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 112

6. Claims 13-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear in Claim 13 what is the correlation between the method step c) of identifying the polypeptide and the method step d) of quantitating the amount of identified polypeptide. In

Art Unit: 1639

what ways is the quantitating step related to the method of identifying a polypeptide? Further, from the specification (pg. 6, lines 16-31 and pg. 7, lines 12-28) the method of identifying the polypeptide involves different method steps from the method of quantitating the polypeptide. In quantitating the polypeptide, isotopic labels and internal standard are used.

Claim Rejections - 35 USC § 102

7. Claims 1-2 and 8-12 rejected under 35 U.S.C. 102(b) as being anticipated by Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999).

Yates, III and Link et al. disclose a method for identifying a polypeptide. The method includes a determining step of two or more characteristics (Yates, III: figure 3 and 4; pg. 7, right column, line 32-36; pg. 9, right column, line 10-62; and Link et al.: pg. 681, right column, line 4-29), a step that compare the characteristics, and identifying the polypeptide from an annotated polypeptide index (Yates, III: figure 3 and 4; pg. 7, right column, line 58-65; pg. 9, left column, line 52-60; and Link et al.: pg. 681, right column, line 4-29). The method further includes the step of determining one or more additional characteristics, the step of comparing the characteristics to an annotated polypeptide index, and repeating these steps (Link et al.: figure 2(c) and 3; pg. 681, right column, line 4-29 and pg 677, right column, line 44-52; and Yates, III: figure 3, 4, and 6).

These characteristics include polypeptide mass, amino acid composition, or order of elution on a chromatographic medium (Link et al.: figure 1 and 2(d); pg. 676, line 23-37; and Yates, III: figure 7; pg. 12, line 30-32 and continue to pg.13, line 1-2).

Claim Rejections - 35 USC § 103

8. Claims 1, 3, 13-14, and 20-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Mann (*Nat. Biotechnol.*; 17(10):954-955; 1999) or Gygi et al. (*Nat. Biotechnol.*; 17(10):994-999; 1999).

Yates, III and Link et al. references have been disclosed above which fail to explicitly disclose a method for identifying a polypeptide that include the step quantitating the amount of identified polypeptide.

Mann and Gygi et al. teach a method of quantitating the amount of identified polypeptide (Mann: figure 1; and Gygi et al.: figure 2 and 4; pg.995, left column, line 1-8 and continue to right column, line 1-2).

It would have been obvious to one having ordinary skill in this art at the time the invention was made to include the method of quantitating the amount of identified polypeptide, as taught by Mann and Gygi et al., with Yates, III and Link et al. method of identifying the polypeptide in order to determine the relative quantities as well as the identity of the polypeptide in a single automated operation (pg 995, right column, line 1-2).

9. Claims 1, 4-8 and 15-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Masselon et al. (*Anal. Chem.*; 72:1918-1924; 2000).

Yates, III and Link et al. references have been disclosed above which fail to explicitly disclose the method of increasing the accuracy of the mass measured.

Art Unit: 1639

Masselon et al discloses the method of increasing the accuracy of the mass measured (pg 1923, right column, line 9-16).

It would have been obvious to one having ordinary skill in this art at the time the invention was made to include the method of increase the accuracy of the mass measured, as disclosed by Masselon et al, with Yates, III and Link et al. method of identifying the polypeptide in order to maintain the high confidence levels for polypeptide identification by the use of high-accuracy mass measurements (pg 1919, left column, line 12-13).

Masselon et al. discloses the claimed invention except for the range of 100 ppm or greater. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the range of 100 ppm or greater, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 102

10. Claims 1-2, 8-12, 44, 45, and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999).

Yates, III and Link et al. disclose a method for identifying a polypeptide. The method includes a determining step of two or more characteristics (Yates, III: figure 3 and 4; pg. 7, right column, line 32-36; pg. 9, right column, line 10-62; and Link et al.: pg. 681, right column, line 4-29), a step that compare the characteristics, and identifying the polypeptide from an annotated

Art Unit: 1639

polypeptide index (Yates, III: figure 3 and 4; pg. 7, right column, line 58-65; pg. 9, left column, line 52-60; and Link et al.: pg. 681, right column, line 4-29). The method further includes the step of determining one or more additional characteristics, the step of comparing the characteristics to an annotated polypeptide index, and repeating these steps (Link et al.: figure 2(c) and 3; pg. 681, right column, line 4-29 and pg 677, right column, line 44-52; and Yates, III: figure 3, 4, and 6). These characteristics include polypeptide mass, amino acid composition, or order of elution on a chromatographic medium (Link et al.: figure 1 and 2(d); pg. 676, line 23-37; and Yates, III: figure 7; pg. 12, line 30-32 and continue to pg.13, line 1-2). Therefore, the methods of both Yates, III and Link et al. anticipate the instant claimed method.

Claim Rejections - 35 USC § 103

11. Claims 1, 44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999).

Yates, III and Link et al. disclose a method for identifying a polypeptide. The method includes a determining step of two or more characteristics (Yates, III: figure 3 and 4; pg. 7, right column, line 32-36; pg. 9, right column, line 10-62; and Link et al.: pg. 681, right column, line 4-29), a step that compare the characteristics, and identifying the polypeptide from an annotated polypeptide index (Yates, III: figure 3 and 4; pg. 7, right column, line 58-65; pg. 9, left column, line 52-60; and Link et al.: pg. 681, right column, line 4-29). The method further includes the step of determining one or more additional characteristics, the step of comparing the characteristics to an annotated polypeptide index, and repeating these steps (Link et al.: figure

Art Unit: 1639

2(c) and 3; pg. 681, right column, line 4-29 and pg 677, right column, line 44-52; and Yates, III: figure 3, 4, and 6). These characteristics include polypeptide mass, amino acid composition, or order of elution on a chromatographic medium (Link et al.: figure 1 and 2(d); pg. 676, line 23-37; and Yates, III: figure 7; pg. 12, line 30-32 and continue to pg.13, line 1-2).

The methods of Yates, III and Link et al. do not expressly disclose that the type of ion exchange chromatography for determining the characteristics of the polypeptides is anion exchange chromatography.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the type of ion exchange chromatography for determining the characteristics of the polypeptides is anion exchange chromatography in the method of Yates, III and Link et al. One of ordinary skill in the art would have been motivated to include the type of ion exchange chromatography for determining the characteristics of the polypeptides is anion exchange chromatography in the methods of Yates, III and Link et al. because the type of ion exchange chromatography for determining the characteristics of the polypeptides would be a choice as experimental design and is considered within the purview of the prior art.

Response to Arguments

12. Applicant's arguments in view of the rejection under 35 U.S.C. 112, second paragraph, of Claims 13-23 as being indefinite filed on 2/18/03 have been fully considered but they are not persuasive.

Art Unit: 1639

Applicant contends that amending the preamble of claim 13 to recite a method of identifying “and quantitating” a polypeptide to refer to the quantitating of step (d) would overcome the rejection under 35 U.S.C. 112, second paragraph.

It is the examiner position that the addition of “and quantitating” to the preamble of claim 13 does not overcome the rejection under 35 U.S.C. 112, second paragraph. There is no correlation between the method step c) of identifying the polypeptide and the method step d) of quantitating the amount of identified polypeptide. The specification (pg. 6, lines 16-31 and pg. 7, lines 12-28) discloses that the method of identifying the polypeptide involves different method steps from the method of quantitating the polypeptide. In quantitating the polypeptide, isotopic labels and internal standard are used. Therefore, the method of claim 13 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

13. Applicant's arguments in view of the rejection under 35 U.S.C. 102(b) of Claims 1-2 and 8-12 as being anticipated by Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) filed on 2/18/03 have been fully considered but they are not persuasive.

Applicant alleges that in both Yates and Link et al. the “polypeptide index” is database of predicted values and it is not from the ‘empirically determine characteristic’ (as claimed in claim 1). Therefore, Yates or Link et al. do not anticipate the presently claimed method for identifying a polypeptide.

Art Unit: 1639

It is the examiner position that Yates or Link et al. do anticipate the presently claimed method for identifying a polypeptide. The database of both Yates and Link et al. is from the 'empirically determine characteristic' because the predicted values are derived from observed values (Yates: pg. 9, lines 52-60; Link: pg. 681, lines 30-45).

14. Applicant's arguments in view of the rejection under 35 U.S.C. 103(a) of Claims 1, 3, 13-14, and 20-23 as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Mann (*Nat. Biotechnol.*; 17(10):954-955; 1999) or Gygi et al. (*Nat. Biotechnol.*; 17(10):994-999; 1999) filed 2/18/03 have been fully considered but they are not persuasive.

Applicant contends that Yates or Link et al. in combination with Mann or Gygi et al. is not obvious from the presently claimed method for identifying a polypeptide. Because in both Yates and Link et al. the "polypeptide index" is database of predicted values and it is not from the 'empirically determine characteristic'.

It is the examiner position that Yates or Link et al. in combination with Mann or Gygi et al. is obvious from the presently claimed method for identifying a polypeptide because Yates or Link et al. do anticipate the presently claimed method for identifying a polypeptide.

15. Applicant's arguments in view of the rejection under 35 U.S.C. 103(a) of Claims 1, 4-8 and 15-19 as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Masselon et al. (*Anal. Chem.*; 72:1918-1924; 2000) filed 2/18/03 have been fully considered but they are not persuasive.

Art Unit: 1639

Applicant contends that Yates or Link et al. in combination with Masselon et al. is not obvious from the presently claimed method for identifying a polypeptide. Because in both Yates and Link et al. the "polypeptide index" is database of predicted values and it is not from the 'empirically determine characteristic'.

It is the examiner position that Yates or Link et al. in combination with Masselon et al. is obvious from the presently claimed method for identifying a polypeptide because Yates or Link et al. do anticipate the presently claimed method for identifying a polypeptide.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999.

Art Unit: 1639

The examiner is on *Increased Flex Schedule* and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
May 2, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER